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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: GATELY, MAURICE K. et al.

Serial No.: 09/401,839

Group Art Unit: 1646

Filed: September 22, 1999

Examiner: Mertz, P.

For: PURIFICATION AND CHARACTERIZATION OF CYTOTOXIC LYMPHOCYTE MATURATION FACTOR AND MONOCLONAL ANTIBODIES THERETO

Attorney Docket No.: 1803-247

Considered by Examiner pm 8/1/02

SECOND DECLARATION OF DR. DAVID H. PRESKY

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, DAVID H. PRESKY, PH.D., do declare that:

1. I am currently head of the Biochemical Assay Development and High Throughput Screening Unit, and am a Project Leader in the Oncology Department of Hoffmann-La Roche Inc., assignee of the captioned patent application.

2. I have extensive experience in molecular biology and immunology. One of my prime research interests has been the study of cytokines and their role in signal transduction-mediated regulation of normal and pathologic immune-related processes. In particular, I have been extensively involved in the study of the cytokine IL-12, which is also known as natural killer stimulatory factor (NKSF) and cytotoxic lymphocyte maturation factor (CLMF), and have published numerous research articles relating to this topic. A copy of my curriculum vitae is attached hereto as Exhibit 1.

3. I hold a Ph.D. in Pharmacology, which I received in 1985 from Harvard University. From 1985 to 1988 I was a postdoctoral fellow in the laboratory of Dr. Ethan M. Shevach, Lab of Immunology, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD.

4. I joined Hoffmann-La Roche Inc. ("Roche") in 1988 as a senior scientist in Molecular Genetics. From 1991 to 1998 I was affiliated with Roche's Inflammation/Autoimmune Diseases Department. In 1998 I began my current position as a project leader in Roche's Oncology Department, and in 1999 began my present, concurrent position as Head of Roche's Biochemical Assay Development and High Throughput Screening Unit.

5. As summarized on my attached curriculum vitae, I have authored or co-authored numerous scientific publications, have received several honors and awards and belong to or serve on various professional societies and committees.

6. I have read and am familiar with United States Patent No. 5,811,523 (the "'523 patent"), which describes purification and cloning of NKSF. I have also read and am familiar with U.S. patent application Serial Nos. 307,817 ("'817 application") and 269,945 (the "'945 application"). As discussed below, it is clear that the '817 and '945 applications fail to describe or teach how to make the full scope of the antibodies claimed in the '523 patent. Nor do these applications describe a practical way of using antibodies which specifically bind NKSF. In particular, the '817 and '945 applications do not provide a practical therapeutic use or a practical diagnostic use for such antibodies.

7. The '817 and '945 applications do not adequately describe how to make the full range of antibodies claimed. Taking just one example, there is no description in the '817

and '945 applications of an antigen, use of such an antigen, or screening methods for resultant antibodies that would allow one of skill in the art to routinely produce antibodies, especially monoclonal antibodies, which specifically bind the 30-35 kD NKSF subunit. The '817 and '945 applications merely state that NKSF polypeptides, in conjunction with standard methods, can be used to generate NKSF antibodies ('817 application, p. 25, ll. 8-11; '945 application, p. 18, ll. 14-17). The '817 and '945 applications fail to teach that the heterodimeric NKSF polypeptide antigen would represent a poor starting material for generation of antibodies directed against the 30-35 kD subunit. That is, generation of antibodies, especially monoclonal antibodies, which specifically bind the NKSF 30-35 kD subunit is difficult, and clearly not routine, when using purified NKSF or reconstituted NKSF heterodimer as the antigen due to the apparent immunodominance of the p40 subunit. The applications also fail to describe screening methods (*e.g.*, screening using the 30-35 kD subunit) to characterize resultant antibodies and identify antibodies that react with the 30-35 kD subunit. The '945 application, in fact, fails to even recognize the existence of a distinct 30-35 kD subunit, but, rather, describes NKSF as a homodimer of 40 kD subunits ('945 application, p. 3, ll. 10-12).

8. The '817 and '945 applications state that NKSF antibodies can be generated using "standard methods for diagnostic or therapeutic use" ('817 application, p. 25, ll. 8-11; '945 application, p. 18, ll. 14-17). No other discussion, however, relating to the use of NKSF antibodies as part of a diagnostic or therapeutic use is to be found in the '817 application or '945 application. The '817 and '945 applications only propose that certain diseases or disorders (e.g., cancer, bacterial or viral infections, immune cell deficiencies) could be treated by administering NKSF polypeptides or fragments thereof. These applications do not teach administration of NKSF antibodies for therapeutic use.

9. Importantly, the therapeutic uses stated in the '817 and '945 applications require an increase in NKSF activity or an enhancement of natural killer (NK) cells, a cell

type whose activity is increased by NKSF. Because of this, even if NKSF antibody administration had been contemplated by the '817 and '945 applications, NKSF antibodies exhibiting an ability to increase NKSF activity or enhance NK cell function would not routinely be obtained via "standard methods" in the absence of any additional teaching (*e.g.*, additional description of starting antigens, or any teaching regarding screening methods to characterize antibodies). Rather, NKSF antibodies obtained via "standard methods" would generally either have no effect on either NKSF activity or NK cell function, or would decrease or abolish ("neutralize") NKSF activity or NK cell function, *i.e.*, the effect would be the opposite of an enhancing or increasing effect.

10. The '817 and '945 applications also fail to teach practical diagnostic uses employing NKSF antibodies. First, the '817 and '945 applications are absolutely silent regarding diagnostic uses whatsoever, except for the statement that diagnostic uses could be performed. The '817 and '945 applications provide no information, however, that would adequately teach one of skill in the art how an NKSF antibody could practically be used for a diagnostic purpose.

11. In particular, the '817 and '945 applications fail to teach that such a diagnostic use could only be performed with certain types or sets of NKSF antibodies exhibiting particular characteristics. This is because the conditions that promote production of biologically active NKSF heterodimer also promote production and secretion of free NKSF 40 kD subunit, which does not exhibit the heterodimeric activity. Thus, a successful antibody-based diagnostic use would require employing an antibody or antibodies that can somehow distinguish between the 70 kD NKSF heterodimer and the free 40 kD NKSF subunit (e.g., a single antibody or combination of antibodies which can distinguish between the 70 kD heterodimer and the free subunits, especially the 40 kD subunit). The '817 and '945 applications fail, however, to point out this requirement for a diagnostic use, and also fail to teach how to make such antibodies, describe starting antigens from which such

antibodies could routinely be generated, or describe screening methods by which antibodies exhibiting the desired characteristics could be identified.

12. I further declare that all statements made in this Declaration are of my own knowledge and are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 7/24/00

David H. Presky, Ph.D.

Attachments:

Exhibit 1: Curriculum Vitae of David H. Presky, Ph.D.

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Employment

1999 - Present	Head, Biochemical Assay Development and High Throughput Screening Unit, Department of Screening Technologies, Hoffmann-La Roche Inc., Nutley, NJ
1998 - Present	Project Leader, MDM2 Antagonists, Oncology Department, Hoffmann-La Roche Inc., Nutley, NJ
1997 - 1998	Project Leader, Vitamin D_3 and Th1/Th2 Cells, Inflammation/Autoimmune Diseases, Hoffmann-La Roche Inc., Nutley, NJ
1996 - 1997	Research Leader, Inflammation/Autoimmune Diseases, Hoffmann-La Roche Inc., Nutley, NJ
1995 - 1996	Research Investigator, Inflammation/Autoimmune Diseases, Hoffmann-La Roche Inc., Nutley, NJ
1991 - 1995	Associate Research Investigator, Inflammation/Autoimmune Diseases, Hoffmann-La Roche Inc., Nutley, NJ
1988 - 1991	Senior Scientist, Molecular Genetics, Hoffmann-La Roche Inc., Nutley, NJ
1985 - 1988	Postdoctoral Fellow with Dr. Ethan M. Shevach, Chief of Cellular Immunology Section, Lab of Immunology, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD
1979 - 1982	Teaching Fellow, Department of Biological Chemistry, Harvard Medical School, Boston, MA
1977 - 1978	Laboratory Instructor, Department of Chemistry, University of Rochester, Rochester, NY

Education

1985	Ph.D., Pharmacology, Harvard University, Cambridge, MA
1980	A.M., Pharmacology, Harvard University, Cambridge, MA
1978	B.S., Chemistry, Magna Cum Laude, University of Rochester, Rochester, NY

Honors and Awards

1985 - 1988	Arthritis Foundation Postdoctoral Fellowship
1983	Endocrine Society Travel Fellowship
1981 - 1985	Albert J. Ryan Foundation Fellowship
1978 - 1981	U.S. Public Health Service Traineeship, Department of Pharmacology, Harvard Medical School, Boston, MA
1978	Merck Index Award for Outstanding Achievement in Chemistry, University of Rochester, Rochester, NY
1978	Elected to Phi Beta Kappa

Professional Societies

American Association of Immunologists
American Chemical Society
American Society for Cell Biology

Professional Committees

1995 - Present	Univ. of Medicine and Dentistry of New Jersey, External Peer Review Committee
1995 - 1999	Hoffmann-La Roche Inc., Radiation Safety Committee

Management Training

"Innovation Management and Creativity", November 18., 1998, Distinctions, Inc., Nutley, NJ
"Success Through Personal Responsibility", June 18, 1998, Career Dimensions, Inc., Nutley, NJ
"Managing for Equal Opportunity", February 3, 1998, Hoffmann-La Roche, Nutley, NJ
"The Seven Habits of Highly Effective People", January 12-14, 1998, Franklin Covey Co., New York, NY
"The Role of the Process Owner", December 5, 1997, Hammer and Company, Boston, MA
"Managing the Process-Centered Enterprise: Principles and Practices", December 3-4, 1997, Hammer and Company, Boston, MA
"Communicating for Results", November, 20, 1991, Hoffmann-La Roche, Nutley, NJ
"Targeted Selection", October 30, 1989, Hoffmann-La Roche, Nutley, NJ
"Managing Performance", September 15, 1988, Hoffmann-La Roche, Nutley, NJ

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Abstracts

Wang, S.X., Podlaski, F.J., Wilkinson, V.L., Stern, A.S., Presky, D.H., and Magram, J. (1997) Characterization of ^{125}I-mouse IL-12 p40 homodimer binding to mouse IL-12 receptor subunits. FASEB J. *11*, A1164 (Abstract)

Wilkinson, V.L., Carvajal, D., Minetti, L.J., Chua, A.O., Gubler, U., Gately, M.K., and Presky, D.H. (1997) Functional characterization of mouse IL-12 receptors. J. Allergy Clin. Immunol. *99*, S52 (Abstract)

Presky, D.H., Minetti, L.J., Gubler, U., Stern, A.S., Chizzonite, R., and Gately, M.K. (1996). Analysis of the multivalent interactions between IL-12 and the high affinity IL-12 receptor (IL-12R) complex. American Association of Immunologists Annual Meeting. FASEB J. *10*, A1310 (Abstract)

Gubler, U., Presky, D., Minetti, L., Chua, A., Yang, H., Nabavi, N., and Gately, M. (1996). Molecular characterization of interleukin-12 receptors. American Association of Immunologists Annual Meeting. FASEB J. *10*, A1326 (Abstract)

Wu, C.-Y., Warrier, R., Presky, D., and Gately, M. (1996). Regulation of IL-12 receptor expression and IL-12 binding by human PBMC. American Association of Immunologists Annual Meeting. FASEB J. *10*, A1323 (Abstract)

Gately, M., Warrier, R., Carvajal, D., Podlaski, F., Stern, A., Dwyer, C., Higgins, G., Familletti, P., Wilkinson, V., Presky, D., Alber, G., Lad, N., Hutchings, A., and Bradshaw, D. (1995). Studies on IL-12 and IL-12 p40 homodimer, an IL-12 antagonist. IL-12: Cellular and Molecular Immunology of an Important Regulatory Cytokine. Annals New York Acad. Sci. (Abstract)

Presky, D.H., Minetti, L.J., Gillessen, S., Gubler, U., Chizzonite, R.A., Stern, A.S., and Gately, M.K. (1995). Evidence for multiple sites of interaction between IL-12 and its receptor. IL-12: Cellular and Molecular Immunology of an Important Regulatory Cytokine. Annals New York Acad. Sci. (Abstract)

Trembleau, S., Penna, G., Gregori, S., Magram, J., Presky, D.H., Gately, M.K., and Adorini, L. (1995). The role of endogenous IL-12 in the development of spontaneous diabetes in NOD mice. (Abstract)

Gately, M., Warrier, R., Carvajal, D., Podlaski, F, Stern, A., Dwyer, C., Higgins, G., Familletti, P., Wilkinson, V., Presky, D., Alber, G., Bradshaw, D., Lad, N., Hutchings, A., Hess, H., and Germann, T. (1995). Interleukin-12: A new target for immunosuppressive therapies? International Congress of Immunology. (Abstract)

Wu, C.-Y., Warrier, R., Carvajal, D., Chua, A., Minetti, L., Mongini, P., Presky, D., Gubler, U., and Gately, M. (1995). Biological function and distribution of human IL-12Rβ chain. Amer. Assoc. Immunol. Meeting. (Abstract)

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